



Methodological Note

**EFPIA & Local Industry Association Disclosure
Codes**

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1.0 INTRODUCTION

Amgen is committed to transparent interactions with Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs). Our interactions take place through collaboration during early scientific research, clinical trials, medical and scientific education all of which are intended to advance patient care by bringing innovative medicines to patients.

HCPs and HCOs are the primary point of contact with patients, they offer expert knowledge on patients' behaviour and management of diseases. This plays a major role in informing Amgen's efforts to improve patient care and treatment options – which is essential to improving patient outcomes. We compensate HCPs and HCOs for the valuable insights and time they offer, we also provide funding for medical education either directly to HCPs, via HCOs or third party specialist providers.

Disclosing Transfers of Value (ToV) such as payments and other benefits e.g. travel and accommodation costs we make to HCPs and HCOs will enhance the public understanding of why interactions are necessary to improve patient care. The pharmaceutical industry associations in each EFPIA country have introduced a Disclosure Code or countries have implemented laws on disclosure, Amgen will comply with the Codes or laws applicable in each country we operate; conducting business with strong ethical principles and with the strictest integrity.

In line with the Disclosure Code or law requirements, Amgen will publicly disclose the ToV it makes to HCPs and HCOs.

In this document (hereafter 'Note') Amgen summarizes the methodologies used to prepare the disclosures and identify ToV.

2.0 SCOPE

This Note applies to the 33* countries¹ who are members of the European Federation of Pharmaceutical Industries & Associations (EFPIA) and Luxemburg where Amgen has interactions with Healthcare Professionals or Healthcare Organizations.

Amgen discloses any support provided to Patient Organizations in accordance with the EFPIA Code of Practice on Relationship Between Pharmaceutical Industry and Patient Organizations. Latest disclosure reports can be found here [Link](#).

Support provided by the Amgen Foundation² can be found here [Link](#).

¹ Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey, Ukraine and UK

² The Amgen Foundation seeks to advance excellence in science education to inspire the next generation of innovators, and invest in strengthening communities where Amgen staff members live and work.

3.0 DEFINITIONS

[Link](#) to the **EFPIA Disclosure Code** – Schedule 1 to learn more about the code, its definitions and the general reporting requirements.

4.0 DATA COLLECTION FOR DISCLOSURE & IDENTIFICATION OF RECIPIENTS

4.1 HOW AMGEN COLLECTS AND PROCESSES DATA

4.1.1 DATA COLLECTION

Transfers of Value (ToV) to a HCP or HCO in an EFPIA country can be provided by any Amgen entity across the world.

Global and regional internal processes apply to interactions with HCPs and HCOs. These processes ensure interactions have a legitimate purpose and data is collected consistently, ensuring accuracy and capture of the required detail, regardless of the Amgen entity or the location of the interaction.

ToV can be provided:

- Directly by Amgen to HCPs and HCOs e.g. payments for services a HCP/HCO provides to Amgen, or
- Indirectly by 3rd Parties e.g. accommodation, travel or registration fees for HCPs to attend medical education events.

Contracts, with 3rd parties who provide any ToV to HCPs or HCOs on behalf of Amgen, mandate the collection of transparency related ToV with the required accuracy and detail; oversight is maintained by Amgen. In principle, meals and drinks do not fall within the scope of the transparency obligations and should not be disclosed, but when they are an integral or inseparable part of the ToV (e.g. included in the registration fee, hotel room rate) they will not be filtered out.

Note: Meals are reportable in a small number of EFPIA countries - based on national laws. Refer to the “NATIONAL DISCLOSURE CODE / LAW SPECIFICS” section for the countries where this applies.

Amgen will disclose ToV against the HCP or HCO with whom we have a contract and pay.

Transactions collected from different Amgen entities will be reviewed by the Amgen subsidiary / legal entity responsible for the disclosure. If Amgen has no legal entity in a particular EFPIA country, the Amgen entity with oversight of that country will conduct the data review and disclosure activities. Refer to the ‘REPORTING’ section for more information.

4.1.2 DATE USED FOR DATA COLLECTION

Direct payments made by Amgen, generated through our financial system, will use the date the transaction was paid as the date of collection of the ToV. This approach is applicable to single and multi year contracts which may result in multiple ToV.

In case of indirect payments (e.g. conferences where accommodation and/or travel is booked or registration fees are paid on behalf of HCPs or HCOs) all relevant expenses are collected from our 3rd Party Suppliers and imported into the Amgen data collection system. Preferably the conference or meeting date is captured as the date of collection of the ToV, where this is not possible the payment date of the ToV is used.

Amgen will collect ToV for services both provided and paid as of 1st January each year and will report within the first 6 months of the following year or earlier as required by specific countries. To meet reporting requirements Amgen will close data processing activities for ToV made in the previous year by the end of February. Any ToV processed after this date will be disclosed either by republishing the previous report or inclusion in the disclosure report of the following year.

4.1.3 TAX

Amgen reports Transfers of Values as net, e.g. without value added tax or withholding tax – unless the Disclosure Code / Legal requirements of a country state differently or the collection of net values is not possible through Amgen financial systems. Refer to the 'NATIONAL DISCLOSURE CODE / LEGAL SPECIFICS' section for information on which countries differ from this approach.

4.1.4 CURRENCY MANAGEMENT

Amgen collects transfers of value (ToV) in the original currency in which they were made. The national disclosure report shows ToV in the country's own currency. Exchange rates are based on the approved currency exchange rates used by Amgen's validated financial systems and procedures which are subject to external inspection by independent auditors.

4.1.5 UNIQUE IDENTIFIERS

Unique Country Local Identifiers (numbers) are provided in those countries where the local code or law mandates, and where the applicable data privacy laws and regulations allow.

4.1.6 IF PLANNED TRANSFER OF VALUE DOES NOT TAKE PLACE

Genuine last minute cancellations of travel or accommodation made on behalf of HCPs or HCOs may occur due to emergency situations. Expenditure associated with such cancellations or unrecoverable spend is not attributed to the named HCP or HCO as no ToV took place.

4.2 IDENTIFICATION OF RECIPIENTS

4.2.1 CLEARLY IDENTIFIABLE RECIPIENT AND COUNTRY

Amgen has internal processes to ensure all transfers of value made to HCPs and HCOs are collected and reconciled in Amgen data collection and review tools. Amgen utilizes both an internal and a proprietary commercial database from which both name and preferentially business address are taken for disclosure. If a HCP/HCO cannot be found in the proprietary commercial database Amgen will capture the required information for disclosure in its own database. These processes allow us to identify the HCP/HCO who receive the transfer of value and ensure disclosure is reported in the country where the recipient conducts their main business.

4.2.2 CROSS-BORDER PAYMENTS / TRANSFERS OF VALUE

Amgen operates globally, our entities across the world have interactions with HCPs and HCOs in EFPIA countries. Through our internal processes and systems we are able to reconcile ToV made to HCPs and HCOs from EFPIA countries provided by Amgen entities across the world. Amgen's data collection and review tool receives transactions from the various Amgen entities and reconciles them based on the country where the recipient conducts business and where they will be reported. Quality checks are performed by the Amgen reporting entity.

4.2.3 PAYMENTS / TRANSFERS OF VALUE MADE BY 3RD PARTIES ON BEHALF OF AMGEN

Where a third party company represents or acts on behalf of Amgen, Amgen ensures that its respective obligations are fulfilled in a written contract outlining how its obligations under the Disclosure Codes will be fulfilled.

4.2.4 EDUCATION OF HCPs THROUGH HCOs

If Amgen provides ToV for medical education of HCPs through a HCO we will disclose the ToV against the HCO. If Amgen selects the individual HCPs who benefit from the educational event conducted by the HCO we will disclose individually under the name of each HCP if they have provided consent under the relevant data privacy law. Refer to section 6 for more information.

4.2.5 UNIVERSITIES AND TEACHING INSTITUTIONS

ToV will be disclosed under the university or teaching institution which is the recipient of the ToV if Amgen support or involvement benefits a HCP / HCO.

4.2.6 HEALTHCARE PROFESSIONALS WHO OPERATE THROUGH THEIR OWN OR THIRD PARTY COMPANIES

Some HCPs create their own company or work through a company to provide advice and services to the pharmaceutical industry. Amgen will capture the name and address of the company and disclose the ToV against the company as a HCO as required by the Disclosure

Codes. Refer to the 'NATIONAL DISCLOSURE CODE / LEGAL SPECIFICS' section for more information.

4.2.7 CLINICAL RESEARCH ORGANIZATIONS & ETHICS COMMITTEES

A Clinical Research Organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology and medical device industries in the form of research services outsourced on a contract basis. CROs are not healthcare organizations (HCOs), however if Amgen makes ToV to HCPs/HCOs through CROs Amgen will disclose the indirect ToV in the relevant disclosure category.

An Ethics Committee is designated to approve, monitor, and review biomedical and behavioral research involving humans. Amgen will never make payments to HCPs individually via an Ethics Committee.

5.0 CATEGORIES OF DISCLOSURE

5.1.1 DONATIONS AND GRANTS TO HCOs

Amgen provides ToV as Grants or Donations to not for profit HCOs to:

- Support science, technology, medicine, healthcare, research or education;
- Educate the public on disease states, medical conditions, science, or technology;
- Further genuine philanthropic and charitable purposes that are consistent with Amgen's scientific and disease-state interests.

Such donations are formalised in contracts that describe the purpose of the donation and the related ToV. If a 'donation in kind' is provided to a HCO e.g. Amgen staff time, a monetary value will be attributed to the 'in kind' donation for the purpose of disclosure.

Donations and grants will be disclosed under "Donations and Grants" in the disclosure reports.

The provision of humanitarian aid in the form of Amgen medicinal products, will be disclosed in the Donations & Grants category.

5.1.2 CONTRIBUTION TO COST OF EVENTS

Amgen provides ToV to HCPs and HCOs for educational support at medical/educational events or congress for:

- TRAVEL AND ACCOMMODATION

Including the cost of flights, trains, car hire, tolls, parking fees, taxis and hotel accommodation, etc.

- REGISTRATION FEES

The cost of registration fees for a HCP to attend a medical / educational event or congress.

5.1.3 SPONSORSHIP AGREEMENTS WITH HCOs / THIRD PARTIES APPOINTED BY HCOs TO MANAGE AN EVENT

Amgen provides ToV when sponsoring a HCO event or project. Where a third party company is a conference or event organizer acting on behalf of a HCO, Amgen will make every effort to disclose ToV against the beneficiary HCO(s) even when the payment is made to the third party company. Agreements are formalised in contracts that describe the purpose of the sponsorship, the benefits Amgen receive and the related ToV. If the sponsorship includes registration fees, travel and accommodation, these will be disclosed separately in the relevant categories in the name of the HCO, unless the recipient HCP is known to Amgen whereby we will disclose against the individual if we have the necessary consent. Agreements generally relate to rental of booth space, advertisement space, drinks and meals provided by the event organizer and satellite symposia at a medical / scientific congress.

Where an event is organized by multiple HCOs cost will be apportioned accordingly.

5.1.4 FEE FOR SERVICE AND CONSULTANCY

Amgen provides ToV for services Amgen receives from HCPs/HCOs under service agreements. Services generally relate to advice on Amgen pipeline or marketed products, speaker fees, speaker training, data analysis, development of educational materials, retrospective non-interventional clinical studies or consulting / advising on future Amgen programs or projects. This will be disclosed under “Fee for Service and Consultancy” in the disclosure reports.

Cost of travel and hotel accommodation associated with services Amgen receive will be disclosed under “Service Related Expenses” in the disclosure reports.

5.1.5 RESEARCH AND DEVELOPMENT TRANSFERS OF VALUE

Amgen is an innovative company with compounds in early research and products in development undergoing clinical trials. We provide ToV to HCPs or HCOs related to the planning or conduct of non-clinical studies (e.g. laboratory), clinical trials and non-interventional studies³.

Research and Development ToV in each reporting period are disclosed on an aggregated basis (without reference to names or addresses of recipients). Costs related to events that are considered essential to effective study conduct e.g. Investigator Meetings, Steering Committee Meetings, Data Monitoring Committees are included in the aggregate amount in the “Research and Development Transfer of Value” category.

Amgen will not publish any information what would be seen as commercially sensitive, in compliance with relevant laws and regulations.

³ Non-Interventional Studies are designed to answer specific questions about a new drug treatment when its prescribed by a HCP to a patient.

6.0 DATA PRIVACY / PROTECTION

6.1.1 MEETING DATA PRIVACY REQUIREMENTS

Data privacy laws exist to protect the personal information of individuals, these laws apply to HCPs in all countries and HCOs in Austria and Switzerland. To ensure Amgen comply with data privacy laws we require HCPs (and where relevant HCOs) consent to Amgen collecting, processing and publishing summary details of the ToV we make during our interactions. If disclosures are required under local law consent may not be required.

Amgen has internal processes to ensure personal information is secure and protected in accordance with all applicable laws.

6.1.2 CONSENT PROCESS

Amgen will obtain the consent, as required, of each HCP (or HCO where required by local privacy laws) to disclose their personal data primarily via data protection, privacy and disclosure clauses in a contract, via a separate consent statement or via a consent statement in an invitation letter supported by a signing in roster of attendees to the event.

6.1.3 AGGREGATE DISCLOSURE

Where consent is required, HCPs (and where relevant HCOs) can withdraw their consent for the individual disclosure of their information at any time. Where their consent is withdrawn or not provided, Amgen will disclose all ToV made to them on an aggregate basis that does not identify them.

If a HCP (or HCO, where applicable) gives only partial consent to any aspect of disclosure, all ToV Amgen made to that HCP (or HCO where applicable) will be disclosed in the aggregate category for the entire reporting period (calendar year), subject to applicable laws.

Partial disclosure under the individual category would be misleading with respect to the nature and scale of the interaction between Amgen and the HCP (HCO), and would not fulfill the intent of transparency through disclosure.

6.1.4 HEALTHCARE PROFESSIONALS AND ORGANIZATIONS' ACCESS TO THEIR DATA

At any time, a HCP/HCO may request a copy of the information Amgen holds about them, including the information on ToV which the company may publish against their name. A HCP or HCO can request data they believe to be inaccurate be corrected. In such cases, Amgen will follow it's internal processes to check and verify the identity of the HCP (or HCO) and the accuracy of the data before making any necessary adjustments to it's public disclosure reports.

To access their data, a HCP/HCO can contact Amgen via the contact details mentioned in their contract with Amgen or by contacting our Global Privacy Office via e-mail: privacyoffice@amgen.com. Amgen will follow it's internal processes to ensure all requests to access personal data are handled within the timelines specified by the relevant country data protection authorities.

7.0 REPORTING

7.1 QUALITY CHECKS PRIOR TO REPORTING

Prior to reporting, Amgen internal processes ensure ToV made to HCPs and HCOs are collected and reconciled in Amgen data collection and review tools. Data quality checks are performed to ensure any HCP (HCO as appropriate) who has not provided consent for individual disclosure are reported in 'aggregate', additional data and process monitoring takes place for quality assurance prior to reporting.

All ToV to a HCP / HCO will be reported in the country where they conduct their main business irrespective of where the interaction occurred.

7.2 LOCATION OF DISCLOSURE REPORTS

7.2.1 PLATFORMS

Unless an EFPIA approved exception applies Amgen discloses ToV in two ways depending on the Disclosure Code or legal requirements of each country:

- on Amgen external webpages and/or
- via central platforms implemented by local industry associations or regulatory bodies in a specific country.

Amgen external webpages are the locations of the disclosure reports in the following countries: Austria, Bulgaria, Croatia, Finland, Germany, Greece, Hungary, Italy, Norway, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Switzerland, the Netherlands and Turkey.

Amgen's corporate external website (www.amgen.com) will be utilized for disclosures where Amgen does not have a legal entity, like Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta, Serbia and Ukraine. Amgen will also disclose ToV to HCPs and HCOs in Luxemburg on this corporate site.

Amgen publishes ToV made to HCPs and HCOs on central platforms in following countries: Belgium, Czech Republic, France, Ireland, Portugal, Romania, Slovakia, Sweden, the Netherlands and UK.

In the event that Amgen has more than one business in a single country ToV are disclosed on a single Amgen webpage in that country (or on the same central platform) for ease of access.

7.2.2 LANGUAGE OF DISCLOSURE REPORTS

Amgen will make reports available in the languages required by each local code or law.

8.0 COUNTRY NATIONAL DISCLOSURE CODE / LAW SPECIFICS

Country	Meals require reporting	Tax (Section 4.1.3)	Other country specifics (Section reference)	Comment / Deviation
Belgium	No		6.1.2	Disclosure mandated by law; consent is not required.
Czech Republic	No	GROSS	3.0; 4.1.3	AIFP clarification: A healthcare professional is a person who, in the course of his/ her professional activities, can prescribe or provide medicinal products. Nurses and other members of the healthcare community cannot prescribe or provide medicinal products and are therefore not subject to disclosure reporting.
Denmark	No	-		Local law: Responsibility for disclosure resides with the HCP and HCO for the ToV.
France	Yes	GROSS	4.1.3; 6.1.2	Disclosure mandated by law; consent is not required.
Germany	No	-	4.2.6	HCPs are considered as HCOs only when there is more than one owner and / or the HCO is officially registered as a legal entity (e.g. GmbH)
Greece	No	-	6.1.2	<p>Under local law 4316/2014, Article 66 par. 7 disclosure of Transfers of Value (ToV) should take place at individual level for both HCP and HCOs and at aggregate level for R&D activities. However, the Hellenic Data Protection Authority, following a request from SFEE and an intervention by EOF regarding the procedure for the implementation of this provision, issued Opinion No. 5/2016 of 29 June 2016, concluding that the scope of Article 66 paragraph 7 of Law 4316/2014 is limited to Type B promotional events, as defined in the EOF Circular No. 17770/2016.</p> <p>In this frame SFEE member companies decided on June 30, 2016 to disclose on their company websites in aggregate all ToV to HCPs for 2015, without differentiating between Type A and Type B events and in parallel wait for EOF's instructions/guidelines. Disclosure of ToV to HCOs took place at individual level.</p> <p>On June 2017 EOF requested pharma companies to submit, at individual level, for disclosure reasons, to EOF website all ToVs to HCPs in regards to company organized events. There was no request for ToVs to HCPs in regards to 3rd party organized events which are still disclosed at aggregate level only on pharma companies' websites. Local requirements for disclosure are dynamically changing due to the decisions from different competent authorities and Amgen is closely monitoring to ensure compliance.</p>

Country	Meals require reporting	Tax (Section 4.1.3)	Other country specifics (Section reference)	Comment / Deviation
Italy	No	GROSS*	3.0; 4.1.3	Clarifications from Farmindustria: <ul style="list-style-type: none"> - Congress Secretariats are included in the definition of "Health Organisations." - *Withholding tax is included in disclosures.
Portugal	Yes	GROSS	4.1.3; 6.1.2	Disclosure mandated by law; consent is not required.
Romania	No		6.1.2	Disclosure mandated by law; consent is not required.
Slovakia	Yes	GROSS	6.1.2	Disclosure mandated by law (Amendment to Act No. 362/2011 Coll. on Medicinal Products and Medical Devices); biannually by 31 January and 31 July; consent is not required.
	No	GROSS		Additional EFPIA reporting covers Scientific HCOs, (which are not in scope of disclosures mandated by law), non R&D cross-border transfers of value (ToV) and R&D ToV reported in aggregated.
Spain	No	-	6.1.2	Spanish Data Protection Agency (AEPD) report (22nd April 2016) – disclosure considered to be in the public interest; no consent required for disclosures.
Switzerland	No	-	3.0	<u>Art. 133 and 134 Swiss Pharma Cooperative Code:</u> Differences in the scope of definitions for HCPs and HCOs.
The Netherlands	Yes	GROSS	4.1.3; 6.1.2	Disclosure mandated by local code; consent is not required.
United Kingdom (UK)	No	-	4.2.6	<u>ABPI code, Clause 1.9 Supplementary Information:</u> If a HCO consists of only one HCP or other relevant decision maker then it would be subject to the requirements in the Code regarding individual HCPs.

9.0 RELATED REFERENCE DOCUMENTS

EFPIA for the **National Member Associations' Codes** of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and healthcare organizations: [LINK](#).

10.0 DOCUMENT HISTORY

Version	Summary of Changes	Change Summary
1.5	Section 8.0 Country National Disclosure Code/ Law specifics Section 7.2.1 Platforms	Minor edit to remove reference to 2017 (Spain). Minor rewording of first sentence.

Version	Summary of Changes	Change Summary
1.4	Section 8.0 Country National Disclosure Code/ Law specifics	<p>Entries for Belgium, Italy, Romania, Spain & Slovakia added.</p> <p>Entries for Czech Republic & Greece edited to reflect clarifications on definitions and the scope of individual and aggregate disclosure reporting respectively.</p>
1.3	Section 4.1.2 Date used for data collection	Minor edit regarding disclosure of data captured after close of data processing activities for the reporting period.
1.2	<p>Section 7.2 Location of Disclosure Reports</p> <p>Section 8.0 Country National Disclosure Code/ Law specifics</p>	<p>Minor edits made to ensure the section accurately reflects where disclosures are made.</p> <p>Entry for Greece amended to reflect that disclosures of ToV for HCP's will be made in aggregate and will not currently distinguish between Type A and Type B events (alignment of SFEE member companies).</p>
1.1	Section 9.0 Related reference documents	Updated link to the EFPIA webpage
1.0	Amgens Methodological Note	Initial document